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| APPLICATION NO. | FI                   | ILING DATE                   | FIRST NAMED INVENTOR | ATTORNEY DOX: KET NO. | CONFIRMATION NO. |  |  |
|-----------------|----------------------|------------------------------|----------------------|-----------------------|------------------|--|--|
| 10/615,013      | 0/615,013 07/09/2003 |                              | Tsunco Himide        | p23554.de1.doe        | - 8725           |  |  |
| 7055            | 7590                 | 04/07/2005                   |                      | EXA                   | EXAMINER         |  |  |
|                 |                      | ERNSTEIN, P.L.C<br>RKE PLACE | •                    | SASTRI, SATYA B       |                  |  |  |
| RESTON, V       |                      |                              |                      | ART UNIT              | PAPER NUMBER     |  |  |
| ,               |                      |                              |                      | 1713                  |                  |  |  |

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   |   |   |   | 71/1/1/      |  |  |  |  |
|---|---|---|---|---|--------------|--|--|--|--|
|   |   | Applicati   | on No.  | Applicant(s)  |              |  |  |  |  |
| Office Action Summary   |   | 10/615,0  | 13  | HIRAIDE ET AL.  |              |  |  |  |  |
|   |   | Examine   | •   | Art Unit  |              |  |  |  |  |
|   |   | Satya B S   |   | 1713  |              |  |  |  |  |
| <i> The</i><br>Period for Re  | MAILING DATE of this communicate ply  | tion appears on the   | e cover sheet with the d  | correspondence add  | ress         |  |  |  |  |
| THE MAIL - Extensions of after SIX (6) - If the period - If NO period - Failure to re Any reply re-   | ENED STATUTORY PERIOD FOR ING DATE OF THIS COMMUNICA of time may be available under the provisions of 3 MONTHS from the mailing date of this communic for reply specified above, the maximum statuto ply within the set or extended period for reply will, belived by the Office later than three months after that term adjustment. See 37 CFR 1.704(b). | TION. 7 CFR 1.136(a). In no eveation. ays, a reply within the stal ny period will apply and w by statute, cause the app | ent, however, may a reply be tir<br>utory minimum of thirty (30) day<br>ill expire SIX (6) MONTHS from<br>lication to become ABANDONE | mely filed  rs will be considered timely. In the mailing date of this com ID (35 U.S.C. § 133). | nmunication. |  |  |  |  |
| Status  |   |   |   |   |              |  |  |  |  |
| 1)⊠ Resp  | oonsive to communication(s) filed o   | on <i>09 July 200</i> 3.  |   | ·   |              |  |  |  |  |
|   | <b>-</b>  |   |   |   |              |  |  |  |  |
|   |   |   |   |   |              |  |  |  |  |
| Disposition o   | f Claims  |   |   |   |              |  |  |  |  |
| 4a) C<br>5)   | n(s) <u>1-24</u> is/are pending in the appl<br>of the above claim(s) <u>19-24</u> is/are w<br>n(s) is/are allowed.<br>n(s) <u>1-18</u> is/are rejected.<br>n(s) <u>3</u> is/are objected to.<br>n(s) <u>1-24</u> are subject to restriction a   | vithdrawn from cor  |   | 1   |              |  |  |  |  |
| Application P   | apers   |   |   |   |              |  |  |  |  |
| 10)⊠ The c<br>Appli<br>Repla  | specification is objected to by the Extrawing(s) filed on <u>09 July 2003</u> is/a cant may not request that any objection acement drawing sheet(s) including the path or declaration is objected to by   | are: a)⊠ accepte<br>n to the drawing(s) b<br>e correction is requir   | e held in abeyance. See<br>ed if the drawing(s) is ob   | e 37 CFR 1.85(a).<br>jected to. See 37 CFF  |              |  |  |  |  |
| Priority under  | 35 U.S.C. § 119   |   |   |   |              |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) ☐ All b) ☐ Some * c) ☐ None of:  1. ☐ Certified copies of the priority documents have been received.  2. ☐ Certified copies of the priority documents have been received in Application No  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received. |   |   |   |   |              |  |  |  |  |
|   | ferences Cited (PTO-892)  |   | 4) Interview Summary  |   |              |  |  |  |  |
| 3) M Information  | aftsperson's Patent Drawing Review (PTO-t<br>Disclosure Statement(s) (PTO-1449 or PTC<br>/Mail Date <u>10/9/03, 1/6/04,</u>   |   | Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:   | ate Patent Application (PTO-1   | 152)         |  |  |  |  |

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**DETAILED ACTION** 

1. This office action is in response to application filed on July 09, 2003. Claims 1-24 are

now pending in the application.

2. Claims 19-24 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as

being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 2/22/05.

However, if the elected claims directed to a product are subsequently found allowable,

withdrawn process claims which depend from or otherwise include all the limitations of an

allowable product claim will be rejoined.

Claim Objections

3. Claim 3 is objected to because of the following informalities: It is unclear which

synthetic resin particles are referred to by "said synthetic resin particles" and whether it is a

chemical or physical bonding. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomonaga et al. (US 4,222,128).

The prior art to Tomonaga et al. is in regard to composite implant materials comprising a sintered apatite material and a thermoplastic or thermosetting resin. The implant material is prepared from a sintered apatite material by impregnating a thermoplastic or a thermosetting resin into the pores or holes of the sintered apatite material (abstract). The exemplified resins include PMMA, polyester, polyurethane, epoxy resins etc. (column 2, lines 28-45). The configuration of the implant material may vary from columnar shaped composite to various other configurations (column 3, lines 6-20, column 4, lines 1-6). The molar ratio of calcium to phosphorous in the working example is 1.67 (column 3).

The difference between the prior art and the present invention is that the prior art does not teach (a) the impregnation with both an uncrosslinked and an at least partially crosslinked synthetic resins and (b) include particulate calcium phosphate in addition to calcium phosphate block during impregnation process.

The prior art to Tomonaga is in an analogous art and teaches impregnation with either thermoplastic or thermosetting resin. Even though the art does not expressly teach a combination, the idea of combining them flows logically from their having been individually taught in the prior art. Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to include both a thermoplastic or thermosetting resin in the

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impregnation of calcium phosphate block and thereby obtain the present invention. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Furthermore, with regard to the composite body produced by pressing calcium phosphate block, calcium phosphate particles and synthetic resins, it is the examiner's position that the end product must be the same as the product disclosed by the prior art. Where product by process claims are rejected over a prior art product that appears to be the same, the burden is shifted to applicants to establish an unobvious difference, even if the production processes are different. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983). Furthermore, the patentability of a product clam rests on the product formed and not on the method by which it is produced. In re Thorpe, 227, USPQ 984 (Fed. Cir. 1985).

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## Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satya Sastri at (571) 212 1112.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached at (571) 212 1114.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SATYA SASTRI

March 22, 2005

IATYANA ZALUKAEVA PRIMARY EXAMINER